IMPORTANT FEATURES ABOUT THE PHS 398 PDF FORMS

The **PHS 398 and PHS 2590 Rich Text File (RTF) and Portable Document File (PDF) Form pages as provided are acceptable by NIH.** All other sections of the application (e.g., Biographical Sketch, Introduction, if necessary, and the Research Plan) must conform to the following four requirements:

1. The height of the letters must not be smaller than 10 point; Helvetica or Arial 12-point is the NIH-suggested font.
2. Type density, including characters and spaces, must be no more than 15 characters per inch (cpi).
3. No more than 6 lines of type within a vertical inch;
4. Margins, in all directions, must be at least ½ inch.

You may substitute computer-generated facsimiles for government-printed forms; however, they must maintain the exact wording and format of the government-printed forms, including all captions and spacing. The PHS 398 and 2590 includes Form Pages and Format Pages. The format pages are intended to assist you in the development of specific sections of the application. Format Pages have been left "unprotected" to allow you to format text, insert graphics, diagrams, or tables. Alternatively, you may create a page similar to the format provided and inclusive of requisite information.

SBIR/STTR Applicants. All SBIR/STTR applications (Phase I, Phase II, and Phase I/Phase II Fast-Track) must be prepared using the PHS 398 Forms in accordance with Chapter VI of the PHS 398 instructions.

Department of Health and Human Services
Public Health Services

Grant Application

Do not exceed 56-character length restrictions, including spaces.

LEAVE BLANK—FOR PHS USE ONLY.

Type	Activity	Number
Review Group		Formerly
Council/Board (Month, Year)		Date Received

1. TITLE OF PROJECT

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION ☐ NO ☐ YES
(If "Yes," state number and title)
Number: Title:

3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR | **New Investigator** ☐ **No** ☐ **Yes**

3a. NAME *(Last, first, middle)* | 3b. DEGREE(S)

3c. POSITION TITLE | 3d. MAILING ADDRESS *(Street, city, state, zip code)*

3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

3f. MAJOR SUBDIVISION

3g. TELEPHONE AND FAX *(Area code, number and extension)*
TEL: FAX:

E-MAIL ADDRESS:

4. HUMAN SUBJECTS RESEARCH
☐ No
☐ Yes

4a. Research Exempt ☐ No ☐ Yes
If "Yes," Exemption No. _____

4b. Human Subjects Assurance No.

4c. NIH-defined Phase III Clinical Trial ☐ No ☐ Yes

5. VERTEBRATE ANIMALS ☐ No ☐ Yes

5a. If "Yes," IACUC approval Date

5b. Animal welfare assurance no

6. DATES OF PROPOSED PERIOD OF SUPPORT *(month, day, year—MM/DD/YY)*		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT	
From	Through	7a. Direct Costs ($)	7b. Total Costs ($)	8a. Direct Costs ($)	8b. Total Costs ($)

9. APPLICANT ORGANIZATION
Name
Address

Institutional Profile File Number (if known)

10. TYPE OF ORGANIZATION
Public: → ☐ Federal ☐ State ☐ Local
Private: → ☐ Private Nonprofit
For-profit: → ☐ General ☐ Small Business
☐ Woman-owned ☐ Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER

DUNS NO. *(if available)*

Congressional District

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
Name
Title
Address

Tel FAX
E-Mail

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
Name
Title
Address

Tel FAX
E-Mail

14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 3a. *(In ink. "Per" signature not acceptable.)*	DATE
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 13. *(In ink. "Per" signature not acceptable.)*	DATE

DESCRIPTION: State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.**

PERFORMANCE SITE(S) *(organization, city, state)*

KEY PERSONNEL. See instructions. *Use continuation pages as needed* to provide the required information in the format shown below. Start with Principal Investigator. List all other key personnel in alphabetical order, last name first.

Name	Organization	Role on Project

Disclosure Permission Statement. Applicable to SBIR/STTR Only. See instructions. ☐ **Yes** ☐ **No**

Principal Investigator/Program Director (Last, first, middle):

The name of the principal investigator/program director must be provided at the top of each printed page and each continuation page.

RESEARCH GRANT

TABLE OF CONTENTS

Page Numbers

Face Page 1

Description, Performance Sites, and Personnel 2-

Table of Contents .....

Detailed Budget for Initial Budget Period (or Modular Budget) .....

Budget for Entire Proposed Period of Support (not applicable with Modular Budget) .....

Budgets Pertaining to Consortium/Contractual Arrangements (not applicable with Modular Budget)

Biographical Sketch—Principal Investigator/Program Director *(Not to exceed four pages)* .....

Other Biographical Sketches *(Not to exceed four pages for each – See instructions))* .....

Resources .....

Research Plan

Introduction to Revised Application *(Not to exceed 3 pages)* .....

Introduction to Supplemental Application *(Not to exceed one page)* .....

A. Specific Aims .....

B. Background and Significance .....

C. Preliminary Studies/Progress Report / Phase I Progress Report (SBIR/STTR Phase II ONLY) .....

D. Research Design and Methods .....

(Items A-D: not to exceed 25 pages)*

** SBIR/STTR Phase I: Items A-D limited to 15 pages.*

E. Human Subjects .....

Protection of Human Subjects (Required if Item 4 on the Face Page is marked "Yes")

Inclusion of Women (Required if Item 4 on the Face Page is marked "Yes") .....

Inclusion of Minorities (Required if Item 4 on the Face Page is marked "Yes") .....

Inclusion of Children (Required if Item 4 on the Face Page is marked "Yes") .....

Data and Safety Monitoring Plan (Required if Item 4 on the Face Page is marked "Yes" ***and*** a Phase I, II, or III clinical trial is proposed) .....

F. Vertebrate Animals .....

G. Literature Cited .....

H. Consortium/Contractual Arrangements .....

I. Letters of Support (e.g., Consultants) .....

J. Product Development Plan (SBIR/STTR Phase II and Fast-Track ONLY) .....

Checklist .....

Appendix *(Five collated sets. No page numbering necessary for Appendix.)*

Check if Appendix is Included ☐

Appendices NOT PERMITTED for Phase I SBIR/STTR unless specifically solicited.

Number of publications and manuscripts accepted for publication *(not to exceed 10)* _____

Other items (list):

Principal Investigator/Program Director (Last, first, middle):

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM	THROUGH

PERSONNEL *(Applicant organization only)*		TYPE APPT. *(months)*	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED *(omit cents)*		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal Investigator						
SUBTOTALS →							

CONSULTANT COSTS		
EQUIPMENT *(Itemize)*		
SUPPLIES *(Itemize by category)*		
TRAVEL		
PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*		
OTHER EXPENSES *(Itemize by category)*		
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		**$** 0
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)* →		**$** 0
SBIR/STTR Only: FEE REQUESTED		

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS		INITIAL BUDGET PERIOD *(from Form Page 4)*	ADDITIONAL YEARS OF SUPPORT REQUESTED 2nd	3rd	4th	5th
PERSONNEL: *Salary and fringe benefits. Applicant organization only.*						
CONSULTANT COSTS						
EQUIPMENT						
SUPPLIES						
TRAVEL						
PATIENT CARE COSTS	INPATIENT					
	OUTPATIENT					
ALTERATIONS AND RENOVATIONS						
OTHER EXPENSES						
SUBTOTAL DIRECT COSTS		0	0	0	0	0
CONSORTIUM/ CONTRACTUAL COSTS	DIRECT					
	F&A					
TOTAL DIRECT COSTS		0	0	0	0	0

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD *(Item 8a, Face Page)* **$** 0

SBIR/STTR Only Fee Requested					

SBIR/STTR Only: Total Fee Requested for Entire Proposed Project Period
(Add Total Fee amount to "Total direct costs for entire proposed project period" above and Total F&A/indirect costs from Checklist Form Page, and enter these as "Costs Requested for Proposed Period of Support on Face Page, Item 8b.) **$** 0

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

BUDGET JUSTIFICATION PAGE MODULAR RESEARCH GRANT APPLICATION				
Initial Budget Period	**Second Year of Support**	**Third Year of Support**	**Fourth Year of Support**	**Fifth Year of Support**
Total Direct Costs Requested for Entire Project Period				$0

Personnel

Consortium

Fee (SBIR/STTR Only)

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY

NOTE: The Biographical Sketch may not exceed four pages. Items A and B (together) may not exceed two of the four-page limit. Follow the formats and instructions on the attached sample.

A. Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

B. Selected peer-reviewed publications (in chronological order). Do not include publications submitted or in preparation.

C. Research Support. List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow the sample format on for each person. (See attached sample). **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Carlucci, Joseph Louis	Professor of Microbiology

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Stanford University	Ph.D.	1964	Infectious Diseases
Harvard Medical School	M.D.	1972	Medicine/Parasitology

A. Positions and Honors.

Positions and Employment

1969-1971 Medical Residency, Internal Medicine, Harvard Medical School
1971-1973 EIS Officer, Hospital Infection Section, Bacterial Diseases Branch, CDC, Atlanta, GA
1973-1974 Instructor and Fellow in Medicine, Hematology, Massachusetts General Hospital, Boston, MA
1974-1975 Instructor in Infectious Diseases, Massachusetts General Hospital, Boston, MA
1978- Senior Associate in Infectious Diseases, Children's Hospital, Boston, MA
1978-1984 Assistant Professor of Pediatrics, Harvard Medical School
1985-1998 Chief, Hemostasis Laboratory, Children's Hospital, Boston, MA
1993- Professor of Pediatrics, Harvard Medical School, Boston, MA
1998- Professor, Dept. of Infectious Diseases, Harvard School of Public Health

Other Experience and Professional Memberships

1972-1973 Acting Chief, National Mucosal Infections Study
1975-2000 Director of Infectious Diseases Laboratory
1975-present Hospital Epidemiologist (Medical Director Infection Control 2000-present), Children's Hospital, Boston
1981-1982 President, Society of Hospital Epidemiologists of America
1988 Member, Society for Pediatric Research
1989-present Medical Director Quality Assurance, Children's Hospital, Boston, MA
1991-1993 Director, American Society for Microbiology, Division F
1991-1997 Hospital Infection Control Practices Advisory Committee, Centers for Disease Control
1998-present Vice-Chair for Health Outcomes, Dept. of Medicine, Children's Hospital
1998-2001 Steering Committee, NACHRI/CDC Pediatric Prevention Network

Honors

1982 SERC Advanced Research Scholarship, Infectious Disease Society of America
2001 Anthony Steinway Award for Excellence in Teaching (Children's Hospital)

B. Selected peer-reviewed publications (in chronological order).

(Publications selected from 133 peer-reviewed publications)

1. Luciani JM, Casper J, Goodman BF, Shaw CM, Carlucci JL. Prevention of respiratory virus infections through compliance with frequent hand-washing routines. N Engl J Med 1988 ;318:389-394.

2. Gussmann J, Pratt R, Sideway DG, Sinclair JM, Emmerson MF, Carlucci JL. Coagulase-negative staphylococcal bacteremia in the changing neonatal intensive care unit population. Is there an epidemic? JAMA. 1988;158:1548-1552.
3. Gussmann J, Carlucci JL, McGovern JE, Jr., Methodologic issues in nursing home epidemiology. Rev Infect Dis 1989;11:1119-1141.
4. Gussmann J, Emmerson MF, Smyth NE, Platt RI, Sidebottom DG, Carlucci JL. Early hospital release and antibiotic usage with nosocomial staphylococcal bacteremia in two neonatal intensive care unit populations. Amer J Dis Child 1991;149:325-339.
5. Murphy JA, Black RW, Schroeder LC, Weissman ST, Gussman JM, Carlucci JL, Short CJ. Quality of care for children with asthma: the role of social factors and practice setting. Pediatrics 1996;98:379-84.
6. Gussmann J, Carlucci JL, McGovern JE, Jr. Incidence of Staphylococcus epidermidis catheter-related bacteremia by infusions. J Infect Dis 1996;172:320-4.
7. Carlucci JL, Huskins WC. Control of nosocomial antimicrobial-resistant bacteria A strategic priority for hospitals worldwide. Clin Infect Dis 1997;S139-S145.
8. Corning WC, Saylor BM, O'Steen C, Gulapagos L, O'Reilly EJ, Carlucci JL. Hospital infection prevention and control: A model for improving the quality of hospital care in low income countries. Infect Control Hosp Epi. 1999;13:123-35.
9. Handler CJ, Marriott B, Clearwater PT, Carlucci JL. Quality of care at a children's hospital: the child's perspective. Arch Pediatr Adolesc Med. 1999;143:1120-7.
10. McKinney D, Poulet KL, Wong Y, Murphy V, Ulright M, Dorling G, Long JC, Carlucci JL, Piper GB. Protective vaccine for Staphylococcus aureus. Science 1999;214:1421-7.
11. Gulazzii L, Kispert ZT, Carlucci JL, Corning WC. Risk-adjusted mortality rates in surgery: a model for outcome measurement in hospitals developing new quality improvement programs. J Hosp Infect 2000;24:33-42.
12. Huebner J, Qui A, Krueger WA, Carlucci JL, Pier GB. Prophylactic and therapeutic efficacy of antibodies to a capsular polysaccharide shared among vancomycin-sensitive and resistant enterococci. Infect Inmmun 2000; 68:4631-6.
13. Levitan O, Sissy RB, Kenney J, Buchwald E, Maccharone AB, Carlucci JL. Enhancement of neonatal innate defense: Effects of adding an recombinant fragment of bactericidal protein on growth and tumor necrosis factor-inducing activity of gram-positive bacteria tested in vivo. Immun 2000;38:3120-25.
14. Garletti JS, Harrison MC, Collin PA, Miller CD, Otter D, Shaker C, Wren M, Carlucci JL, Makato DG. A randomized trial comparing iodine to a alcohol impregnated dressing for prevention of catheter infections in neonates. Pediatrics. 2001;127:1461-6.
15. Corning WC, Barillo K, Festival MR, Lingonberry S, Lumbar P, Peters A, Pursons M, Carlucci JL, Tella JE. A national survey of practice variation in the use of antibiotic prophylaxis in heart surgery. J Hosp Infect. 2001;33:121-5.
16. Hoboken S, Peterson D, Graveldy L, Carlucci JL. Compliance with hand hygiene practice in pediatric intensive care. Pediatric Crit Care Med. 2001;12:211-214.
17. Hasker S, Pittoui D, Gray L, Zaruccii A, Potter G, Seemore MH, Carlucci JL. Interventional study to evaluate the impact of an antibiotic-infused hand gel in improving hand hygiene compliance. Pediatr Infect Dis J. Accepted for publication.
18. Lander C, Summers R, Murray S, Hummer CJ, Carlucci JL. Pediatrics: Is hospital food more nutritional than mom's cooking? Pediatrics 2001;11: 140-145.

C. Research Support

Ongoing Research Support

R01 HS35793 Carlucci (PI) 9/01/99-8/30/04
AHRQ
Reducing Antimicrobial Resistance in Low-Income Communities: A Randomized Trial.
This study is a randomized trial of interventions to reduce antimicrobial usage and resistance in low-income communities.
Role: PI

Ongoing Research Support (cont.)

2 R01 AI12345-05 Carlucci (PI) 4/01/01-3/31/06
NIH/NIAID
Bacteriology and Mycology Study of ICU Patients at Risk for Antimicrobial Resistant Bacterial Infections.
The study will perform clinical trials of interventions to reduce antimicrobial resistant infections.
Role: PI

R01- AI24680-04 Peterson (PI) 3/01/01-2/28/06
NIH/NIAID
Virulence and Immunity to Staphylococci.
This study investigates the production of polysaccharide by *Staphylococcus aureus* and its role in virulence as measured in animal models of infection and its ability to function as a target for protective antibody.
Role: Paid consultant.

2 R01 HL 00000-13 Anderson (PI) 3/01/01-2/28/06
NIH/NHLBI
Chloride and Sodium Transport in Airway Epithelial Cells
The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.
Role: Co-Investigator

5 R01 HL 00000-07 Baker (PI) 4/1/01 – 3/31/04
NIH/NHLBI
Ion Transport in Lungs
The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.
Role: Co-Investigator

1 R01 AI12826-01 Hoffman (PI) 9/28/01-9/27/03
NIH/NIAID
Intermountain Child Health Services Research Consortium
This consortium will seek to build pediatric health services research capacity and training in the Intermountain Region.
Role: Co-Investigator

Completed Research Support

5 RO1 AI10011-05 Herman (PI) 10/01/99 – 11/30/01
NIH/NIAID
Evaluating Quality Improvement Strategies (EQUIS)
The goal of this study was to evaluate quality improvement and collaborative learning to improve asthma care in office-based pediatrics.
Role: Co-Investigator

5 R01 AI098765 Spielman (PI) 7/01/96 -6/30/01
NIH/NIAID
Epidemiology of Emerging Infections #1 T32 AI07654
The goal of this project was to study emerging infections in high risk populations who are treated in emergency room situations.
Role: Co-Investigator

RESOURCES

FACILITIES: Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

Principal Investigator/Program Director (Last, first, middle):

CHECKLIST

TYPE OF APPLICATION *(Check all that apply.)*

☐ NEW application. *(This application is being submitted to the PHS for the first time.)*

☐ SBIR Phase I ☐ SBIR Phase II: SBIR Phase I Grant No. _ _____ ☐ SBIR Fast Track

☐ STTR Phase I ☐ STTR Phase II: STTR Phase I Grant No. _ _____ ☐ STTR Fast Track

☐ REVISION of application number: _____

(This application replaces a prior unfunded version of a new, competing continuation, or supplemental application.)

☐ COMPETING CONTINUATION of grant number: _____

(This application is to extend a funded grant beyond its current project period.)

INVENTIONS AND PATENTS
(Competing continuation appl. and Phase II only)

☐ No ☐ Previously reported

☐ Yes. If "Yes," ☐ Not previously reported

☐ SUPPLEMENT to grant number: _____

(This application is for additional funds to supplement a currently funded grant.)

☐ CHANGE of principal investigator/program director.

Name of former principal investigator/program director: _____

☐ FOREIGN application or significant foreign component.

1. PROGRAM INCOME ***(See instructions.)***

All applications must indicate whether program income is anticipated during the period(s) for which grant support is request. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***

The following assurances/certifications are made and verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. Descriptions of individual assurances/ certifications are provided in Section III. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

•Human Subjects; •Research Using Human Embryonic Stem Cells• •Research on Transplantation of Human Fetal Tissue •Women and Minority Inclusion Policy •Inclusion of Children Policy• Vertebrate Animals• •Debarment and Suspension; •Drug- Free Workplace *(applicable to new [Type 1] or revised [Type 1] applications only)*; •Lobbying; •Non-Delinquency on Federal Debt; •Research Misconduct; •Civil Rights (Form HHS 441 or HHS 690); •Handicapped Individuals (Form HHS 641 or HHS 690); •Sex Discrimination (Form HHS 639-A or HHS 690); •Age Discrimination (Form HHS 680 or HHS 690); •Recombinant DNA and Human Gene Transfer Research; •Financial Conflict of Interest (except Phase I SBIR/STTR) •STTR ONLY: Certification of Research Institution Participation.

3. FACILITIES AND ADMINSTRATIVE COSTS (F&A)/ INDIRECT COSTS. See specific instructions.

☐ DHHS Agreement dated: _____ ☐ No Facilities And Administrative Costs Requested.

☐ DHHS Agreement being negotiated with _____ Regional Office.

☐ No DHHS Agreement, but rate established with _____ Date _____

CALCULATION* *(The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)*

a. Initial budget period:	Amount of base $		x Rate applied		% = F&A costs	$
b. 02 year	Amount of base $		x Rate applied		% = F&A costs	$
c. 03 year	Amount of base $		x Rate applied		% = F&A costs	$
d. 04 year	Amount of base $		x Rate applied		% = F&A costs	$
e. 05 year	Amount of base $		x Rate applied		% = F&A costs	$
					TOTAL F&A Costs	$

*Check appropriate box(es):

☐ Salary and wages base ☐ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.):*

4. SMOKE-FREE WORKPLACE ☐ Yes ☐ No *(The response to this question has no impact on the review or funding of this application.)*

Principal Investigator/Program Director (Last, first, middle):

Place this form at the end of the signed original copy of the application.
Do not duplicate.

PERSONAL DATA ON PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR

The Public Health Service has a continuing commitment to monitor the operation of its review and award processes to detect—and deal appropriately with—any instances of real or apparent inequities with respect to age, sex, race, or ethnicity of the proposed principal investigator/program director. To provide the PHS with the information it needs for this important task, complete the form below and attach it to the signed original of the application after the Checklist. **Do not attach copies of this form to the duplicated copies of the application.**

Upon receipt of the application by the PHS, this form will be separated from the application. This form will **not** be duplicated, and it will **not** be a part of the review process. Data will be confidential, and will be maintained in Privacy Act record system 09-25-0036, "Grants: IMPAC (Grant/Contract Information)." The PHS requests social Security numbers for accurate identification, referral, and review of applications and for management of PHS grant programs. Provision of the Social Security number is voluntary. No individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose his or her Social Security Number. The PHS requests the Social Security Number under Sections 301 (a) and 487 of the PHS Act as amended (42 USC241a and USC288). All analyses conducted on the date of birth and race and/or ethnic origin data will report aggregate statistical findings only and will not identify individuals. If you decline to provide this information, it will in no way affect consideration of your application. Your cooperation will be appreciated.

DATE OF BIRTH *(MM/DD/YY)*	SEX/GENDER ☐ Female ☐ Male
Social Security Number	

ETHNICITY

1. Do you consider yourself to be Hispanic or Latino? (See definition below.) Select one.

Hispanic or Latino. A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."

☐ **Hispanic or Latino**

☐ **Not Hispanic or Latino**

RACE

2. What race do you consider yourself to be? Select one or more of the following.

☐ ***American Indian or Alaska Native.*** A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

☐ ***Asian.*** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

☐ ***Black or African American.*** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black" or African American."

☐ ***Native Hawaiian or Other Pacific Islander.*** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

☐ ***White.*** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

☐ Check here if you do not wish to provide some or all of the above information.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title:

Total Planned Enrollment:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category Total of All Subjects*			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects *			

*The “Ethnic Category Total of All Subjects” must be equal to the “Racial Categories Total of All Subjects.”

Inclusion Enrollment Report Table

This report format should NOT be used for data collection from study participants.

Study Title:

Total Enrollment: _____ **Protocol Number:** _____

Grant Number: _____

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	**Sex/Gender**			
	Females	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree.
** These totals must agree.

RCA TOC Substitute Page Candidate *(Last, first, middle):* _____

Use this substitute page for the Table of Contents of Research Career Awards. The name of the candidate must be provided at the top of each printed page and each continuation page.

RESEARCH CAREER AWARD
TABLE OF CONTENTS
(Substitute Page)

Page Numbers

Section I: Basic Administrative Data

1–3. Face Page, Description and Key Personnel, Table of Contents (Form pages 1, 2, and this substitute page) 1-

4. Budget for Entire Proposed Period of Support (Form page 5) .....

5. Biographical Sketches *(Candidate and Sponsor[s]*—Biographical Sketch Format page) (Not to exceed four pages)*

6. Other Support Pages for the Mentor (not the candidate).....

7. Resources (Resources Format page) .....

Section II: Specialized Information

1. Introduction to Revised Application (Not to exceed 3 pages) .....

2. Letters of Reference (Attach to Face Page)*

3. The Candidate

A. Candidate's Background .....

B. Career Goals and Objectives: Scientific Biography ..... *(Items A-C included in 25 page limit)*.....

C. Career Development Activities during Award Period

4. Statements by Sponsor(s), Consultant(s)*, and Collaborator(s)*

5. Environment and Institutional Commitment to Candidate

A. Description of Institutional Environment.....

B. Institutional Commitment to Candidate's Research Career Development .....

6. Research Plan

A. Statement of Hypothesis and Specific Aims .....

B. Background, Significance, and Rationale ..... *(Items A-D included in 25 page limit)* .....

C. Preliminary Studies and Any Results .....

D. Research Design and Methods .....

E. Human Subjects* .....

List appropriate grants with IRB approval dates or exemption designation .....

F. Vertebrate Animals*.....

List appropriate grants with IACUC approval dates or exemption designation .....

G. Literature Cited .....

H. Consortium/Contractual Arrangements*.....

I. Consultants*.....

7. Checklist

8. Appendix *(Five collated sets. No page numbering necessary)* ☐ Check if Appendix is included

Number of publications and manuscripts accepted or submitted for publication *(not to exceed 6)* _____

List of Key Items:

Note: Type density and size must conform to limits provided in the Specific Instructions.

*Include these items only when applicable.

CITIZENSHIIP

☐ U.S. citizen or noncitizen national

☐ Permanent resident of U.S. (If a permanent resident of the U.S., a notarized statement must be provided by the time of award.

RESEARCH CAREER AWARD REFERENCE REPORT GUIDELINES *(Series K)*

Title of Award:

Type of Award: **Application Submission Deadline: _____**

Name of Candidate (Last, first, middle):

Name of Respondent (Last, first, middle):

The candidate is applying to the National Institutes of Health for a Research Career Award (RCA). The purpose of this award is to develop the research capabilities and career of the applicant. These awards provide up to five years of salary support and guarantee them the ability to devote at least 75–80 percent of their time to research for the duration of the award. Many of these awards also provide funds for research and career development costs. The award is available to persons who have demonstrated considerable potential to become independent researchers, but who need additional supervised research experience in a productive scientific setting.

We would appreciate receiving your evaluation of the above candidate with special reference to:

- potential for conducting research;
- evidence of originality;
- adequacy of scientific background;
- quality of research endeavors or publications to date, if any;
- commitment to health-oriented research; and
- need for further research experience and training.

Any related comments that you may wish to provide would be welcomed. These references will be used by PHS committees of consultants in assessing candidates.

Complete the report in English on 8-1/2 x 11" sheets of paper. Return your reference report to the candidate sealed in the envelope as soon as possible and in sufficient time so that the candidate can meet the application submission deadline. References must be submitted with the application.

We have asked the candidate to provide you with a self-addressed envelope with the following words in the front bottom corner: “DO NOT OPEN—PHS USE ONLY.” Candidates are not to open the references. Under the Privacy Act of 1974, RCA candidates may request personal information contained in their records, including this reference. Thank you for your assistance.

Type the name of the principal investigator/program director at the top of each printed page and each continuation page. (For type specifications, see PHS 398 Instructions.)

INSTITUTIONAL NATIONAL RESEARCH SERVICE AWARD
(Substitute Page)

TABLE OF CONTENTS

Page Numbers

Face Page Description and Personnel, Table of Contents
(Form Pages 1, 2, and this NRSA Substitute Form Page 3) ..... 1- _____
Detailed Budget for Initial Budget Period *(NRSA Substitute Form Page 4)* ..... _____
Budget for Entire Proposed Period of Support *(NRSA Substitute Form Page 5)* ..... _____
Biographical Sketch—Principal Investigator/Program Director *(Not to exceed four pages)* ..... _____
Other Biographical Sketches *(Not to exceed four pages for each)* ..... _____
Resources ..... _____

Research Training Program Plan _____
Introduction to Revised Application *(Not to exceed 3 pages)* ..... _____
Introduction to Supplemental Application *(Not to exceed one page)* ..... _____
A. Background ..... _____
B. Program Plan ..... _____
1. Program Direction ..... _____
2. Program Faculty ..... *(Items A-D: not to exceed 25 pages,* _____
3. Proposed Training ..... *excluding tables*)* _____
4. Trainee Candidates ..... _____
C. Recruitment of Individuals from Underrepresented Racial/Ethnic Groups ..... _____
D. Responsible Conduct of Research ..... _____
E. Progress Report (Competing Continuation Applications Only) ..... _____
F. Human Subjects ..... _____
Protection of Human Subjects (Required if Item 4 on the Face Page is marked "Yes") _____
Inclusion of Women (Required if Item 4 on the Face Page is marked "Yes") ..... _____
Inclusion of Minorities (Required if Item 4 on the Face Page is marked "Yes") ..... _____
Inclusion of Children (Required if Item 4 on the Face Page is marked "Yes") ..... _____
Data and Safety Monitoring Plan (Required if Item 4 on the Face Page is marked "Yes" ***and*** a Phase I, II, or III clinical trial is proposed) ..... _____
G. Vertebrate Animals ..... _____
H. Consortium/Contractual Arrangements ..... _____
Checklist ..... _____

*Type density and size must conform to limits provided in PHS 398 Specific Instructions.

Appendix *(Five collated sets. No page numbering necessary for Appendix.)*

☐ Check if Appendix is included

NRSA Initial Budget Period Substitute Page

Principal Investigator/Program Director: (Last, first, middle)

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY (NRSA Substitute Page)	**FROM**	**THROUGH**
STIPENDS		**DOLLAR TOTAL**
PREDOCTORAL No. Requested:		
POSTDOCTORAL *(Itemize)* No. Requested:		
OTHER *(Specify)* No. Requested:		
TOTAL STIPENDS		
TUITION, FEES, AND INSURANCE *(Itemize)*		
TRAINEE TRAVEL *(Describe)*		
TRAINEE RELATED EXPENSES		
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Also enter on Face Page, Item 7)*		

BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT DIRECT COSTS ONLY (NRSA Substitute Page)

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD *(from Form Page 4)*		ADDITIONAL YEARS OF SUPPORT REQUESTED							
			2nd		3rd		4th		5th	
PREDOCTORAL STIPENDS	No.		No.		No.		No.		No.	
POSTDOCTORAL STIPENDS										
OTHER STIPENDS										
TOTAL STIPENDS				0		0		0		0
TUITION, FEES, AND INSURANCE										
TRAINEE TRAVEL										
TRAINEE RELATED EXPENSES										
TOTAL DIRECT COSTS				0		0		0		0

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD *(Item 8a, Face Page)* **$** 0

JUSTIFICATION. For all years, explain the basis for the budget categories requested. Follow the instructions for the Initial Budget Period and include anticipated postdoctoral levels. No explanation is necessary for Training-Related Expenses.

STTR Research Institution Budget Additional Page Principal Investigator/Program Director: (Last, first, middle)

BUDGET of RESEARCH INSTITUTION (STTR ONLY)	FROM	THROUGH

NAME AND ADDRESS OF RESEARCH INSTITUTION

PERSONNEL					DOLLAR AMOUNT REQUESTED *(omit cents)*		
NAME	ROLE ON PROJECT	TYPE APPT. *(months)*	% EFFORT ON PROJ.	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal Investigator						
SUBTOTALS →							

CONSULTANT COSTS		
EQUIPMENT *(Itemize)*		
SUPPLIES *(Itemize by category)*		
TRAVEL		
PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*		
OTHER EXPENSES *(Itemize by category)*		
TOTAL DIRECT COSTS (also enter as Consortium/Contractual Costs on Budget Page of Small Business Concern)		
FACILITIES and ADMINISTRATIVE COSTS (show calculation) (also enter as Consortium/Contractual Costs on Budget of Small Business Concern)		

CERTIFICATION OF RESEARCH INSTITUTION PARTICIPATION. Through the signature below of the duly authorized representative of the research institution on this "Certification of Research Institution" page, and by way of the signature of the official signing for applicant organization (small business concern) on the Face Page of the application, the small business concern and the research institution certify *jointly* that: (1) the proposed STTR project will be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("cooperative research and development"); (2) the proposed STTR project is a cooperative research or research and development effort to be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("performance of research and analytical work"); and (3) regardless of the proportion of the proposed project to be performed by each party, the small business concern will be the primary party that will exercise management direction and control of the performance of the project. If the research institution is a contractor-operated federally funded research and development center, the duly authorized representative of the contractor-operated federally funded research and development center certifies, *additionally*, that it: (4) is free from organizational conflicts of interests relative to the STTR program; (5) did not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of this STTR grant application; and (6) used outside peer review, as appropriate, to evaluate the proposed project and its performance therein.

Signature of Duly Authorized Representative	Printed Name	Title	Date of Signature

Certification of Research Institution for Small Business Technology Transfer Grants

Through the signature below of the duly authorized representative of the research institution on this "Certification of Research Institution" page, and by way of the signature of the official signing for applicant organization (small business concern) on the Face Page of the application, the small business concern and the research institution certify *jointly* that:

(1) the proposed STTR project will be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("cooperative research and development");

(2) the proposed STTR project is a cooperative research or research and development effort to be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("performance of research and analytical work"); and

(3) regardless of the proportion of the proposed project to be performed by each party, the small business concern will be the primary party that will exercise management direction and control of the performance of the project.

If the research institution is a contractor-operated federally funded research and development center, the duly authorized representative of the contractor-operated federally funded research and development center certifies, *additionall*y, that it:

(4) is free from organizational conflicts of interests relative to the STTR program

(5) did not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of this STTR grant application; and

(6) used outside peer review, as appropriate, to evaluate the proposed project and its performance therein.

Signature of Duly Authorized Representative Date of Signature

Printed Name and Title of Duly Authorized Representative

Research Institution Total Costs =
(Direct costs + F&A Costs)

DO NOT SUBMIT UNLESS REQUESTED

OTHER SUPPORT

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. ***Include the principal investigator's name at the top and number consecutively with the rest of the application.*** The sample is intended to provide guidance regarding the type and extent of information requested. Refer to the specific instructions in Section I. For information pertaining to the use of and policy for other support, see "Policy and Additional Guidance."

Format

NAME OF INDIVIDUAL
ACTIVE/PENDING

Project Number (Principal Investigator) Source Title of Project *(or Subproject)* The major goals of this project are…	Dates of Approved/Proposed Project Annual Direct Costs	Percent Effort

OVERLAP *(summarized for each individual)*

Samples

ANDERSON, R.R.

ACTIVE

2 R01 HL 00000-13 (Anderson) 3/1/1997 – 2/28/2002 30%
NIH/NHLBI $186,529
Chloride and Sodium Transport in Airway Epithelial Cells

The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

5 R01 HL 00000-07 (Baker) 4/1/1994 – 3/31/2002 10%
NIH/NHLBI $122,717
Ion Transport in Lungs

The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.

R000 (Anderson) 9/1/1996 – 8/31/2002 10%
Cystic Fibrosis Foundation $43,123
Gene Transfer of CFTR to the Airway Epithelium

The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

PENDING

DCB 950000 (Anderson) 12/01/2002 – 11/30/2004 20%
National Science Foundation $82,163
Liposome Membrane Composition and Function

The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

OVERLAP

DO NOT SUBMIT UNLESS REQUESTED

OTHER SUPPORT *(continued)*

RICHARDS, L.
NONE

HERNANDEZ, M.
ACTIVE

5 R01 CA 00000-07 (Hernandez) 4/1/1995 – 3/31/2002 40% academic
NIH/NCI
Gene Therapy for Small Cell Lung Carcinoma

The major goals of this project are to use viral strategies to express the normal p53 gene in human SCLC cell lines and to study the effect on growth and invasiveness of the lines.

5 P01 CA 00000-03 (Chen) 7/1/2000 – 6/30/2002 20% academic
NIH/NCI $104,428 (sub only) 100% summer
Mutations in p53 in Progression of Small Cell Lung Carcinoma

The major goals of this subproject are to define the p53 mutations in SCLC and their contribution to tumor progression and metastasis.

BE 00000 (Hernandez) 9/1/1996 – 8/31/2002 20% academic
American Cancer Society $86,732
p53 Mutations in Breast Cancer

The major goals of this project are to define the spectrum of p53 mutations in human breast cancer samples and correlate the results with clinical outcome.

OVERLAP

Potential commitment overlap for Dr. Hernandez between 5 R01 CA 00000-07 and the application under consideration. If the application under consideration is funded with Dr. Hernandez committed at 30 percent effort, Dr. Hernandez will request approval to reduce her effort on the NCI grant.

BENNETT, P.
ACTIVE

Investigator Award (Bennett) 9/1/1999 – 8/31/2002 70%
Howard Hughes Medical Institute $581,317
Gene Cloning and Targeting for Neurological Disease Genes

This award supports the PI's program to map and clone the gene(s) implicated in the development of Alzheimer's disease and to target expression of the cloned gene(s) to relevant cells.

OVERLAP

None

Principal Investigator/Program Director:
(Last, first, middle)

DO NOT SUBMIT UNLESS REQUESTED

Competing Continuation Applications
PERSONNEL REPORT

All Key Personnel for the Current Budget Period

Name	Degree(s)	SSN	Role on Project *(e.g. PI, Res. Assoc.)*	Date of Birth *(MM/DD/YY)*	Annual % Effort

Mailing address for application

Use this label or a facsimile

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE
ROOM 1040 – MSC 7710
BETHESDA, MD 20892-7710

Applicants who wish to use express mail or overnight courier service use this address, but change the zip code to 20817. The telephone number is 301-435-0715.

C.O.D. applications will *not* be accepted.

For application in response to RFA

Use this label or a facsimile

IF THIS APPLICATION IS IN RESPONSE TO AN RFA, be sure to put the RFA number in line 2 of the application face page. In addition, after duplicating copies of the application, cut along the dotted line below and staple the RFA label to the bottom of the face page of the original and place the original on top of your entire package. Failure to use this RFA label could result in delayed processing of your application such that it may not reach the review committee on time for review. ***Do not use*** the label unless the application is in response to a specific RFA. Also, applicants responding to a specific RFA should be sure to follow all special mailing instructions published in the RFA.

RFA No. _____ _____

RFA

Mailing address for application

Use this label or a facsimile

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE
ROOM 1040 – MSC 7710
BETHESDA, MD 20892-7710

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C.O.D. applications will *not* be accepted.

For application in response to SBIR/STTR

Use this label or a facsimile

IF THIS APPLICATION IS IN RESPONSE TO AN SBIR/STTR Solicitation, be sure to put the SBIR/STTR Solicitation number in line 2 of the application face page. In addition, after duplicating copies of the application, cut along the dotted line below and staple the appropriate SBIR or STTR label to the bottom of the face page of the original and place the original on top of your entire package. If this SBIR or STTR application is in response to an RFA, be sure to also include the RFA No. in the space provided below.

SBIR

RFA No. _____(if applicable)

STTR

RFA No. _____(if applicable)